



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/551,475

09/30/2005

Michael George

Q111431

4410

23373 7590 05/12/2009
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

BOESEN, CHRISTIAN C

ART UNIT

PAPER NUMBER

4131

MAIL DATE

DELIVERY MODE

05/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,475	Applicant(s) GEORGE ET AL.	
	Examiner CHRISTIAN BOESEN	Art Unit 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-55, 57, 59, 60, 63-79, 83-84, 86-89 and 91-98 is/are pending in the application.
- 4a) Of the above claim(s) 48-55, 57, 59, 60, 63, 67, 69-79, 83, 84, 86-89 and 92-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47, 64-66, 68 and 91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/20/2009 and 02/27/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 4131

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received 03/13/2009. The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Christian Boesen Art Unit 4131.

Election/Restrictions

Applicant's election with traverse of group IV, claims 47, 64-68, 70, 88-91 is acknowledged. Applicant argues that Faye does not disclose the compound of formula I. In response, the examiner notes that while Faye does not disclose formula I, Faye discloses libraries of fluorescently labeled GPCR ligands. The claims are presently rejected under 103 because McCrea and Burchard teaches the formula of claim I as discussed in the rejection under 35 USC § 103(a) below. Because the prior art teaches the shared technical feature of the present invention the claims lack unity and therefore the restriction is set forth as it applies to U.S. practice. The restriction is thus deemed proper and is made FINAL.

New claims 93-98 were added.

Claims 48-55, 57, 59-60, 63, 67, 69-79, 83-84, 86-89, and 92-98 are withdrawn because they are drawn to the non-elected invention or species.

Claims 47, 64-66, 68, and 91 are under examination in this Office Action.

Art Unit: 4131

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 02/20/2009 and 02/27/2008 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner. It is noted that references missing dates were not considered.

Specification

The disclosure is objected to because of the following informalities. The use of trademarks (i.e. BODIPY™, Cascade Blue™, and Texas Red™) has been noted throughout this application (i.e. page 3, line 3). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 64, 66, 68, and 91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 4131

Claims 64, 66, 68, and 91 contain the trademark/trade names BODIPY™, Cascade Blue™, and Texas Red™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the fluorescent label and, accordingly, the identification/description is indefinite.

[MPEP 2173.05(u)] If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

If a trademark or trade name appears in a claim and is not intended as a limitation in the claim, the question of why it is in the claim should be addressed. Does its presence in the claim cause confusion as to the scope of the claim? If so, the claim should be rejected under 35 U.S.C. 112, second paragraph.

Art Unit: 4131

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 47, 64-66, 68, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrea (Molecular Pharmacology 1996 volume 49 pages 927-937) in combination with (US Patent 6,171,794 B1).

Claims are drawn to a fluorescently tagged nucleoside ligand for adenosine A1 and other G protein coupled receptors. The elected species is BODIPY-630/650 tagged salmeterol. The chemical structure of the elected ligand species corresponds to CAS Registry number 89365-50-4 that is identical to the compound named salmeterol with the CAS Registry number 89365-50-4.

McCrea teaches that salmeterol, which is a ligand for β_1 - and β_2 -adrenoceptors (see entire document). Cells containing stimulated β_1 - and β_2 -adrenoceptors accumulate cAMP (see page

Art Unit: 4131

928 and figure 1). The accumulation of cAMP is measured by stimulating C6 cell monolayers with salmeterol and measuring the conversion of radiolabeled adenine (8-[³H]Adenine) into [³H]cAMP (see table 1 and figures 1-5).

While McCrea teaches using a radiolabel to determine the duration of salmeterol action, McCrea does not expressly teach a fluorescently tagged salmeterol.

Burchard teaches labeling nucleotide analogues with the fluorescent label BODIPY-630/650 (see column 9 line 43 and claim 14).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to label McCrea's salmeterol with Burchard's fluorescent label BODIPY-630/650 to arrive at applicant's invention with the above cited references before them.

One would have been motivated to label McCrea's salmeterol with Burchard's fluorescent label BODIPY-630/650 because Burchard teaches that fluorescent labels are preferred to other types of labeling including radioactive isotopes (see column 9 lines 24-33).

One would have had a reasonable expectation of success to label McCrea's salmeterol with Burchard's fluorescent label BODIPY-630/650 because techniques for labeling nucleotide analogues are well established in the art as evidenced by Burchard (see column 9 lines 24-33).

Thus the present invention would have been *prima facie* obvious at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

Art Unit: 4131

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 47, 64-66, 68, and 91 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21-24 of copending Application No. 11/576,035.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn to a fluorescently tagged nucleoside ligand for adenosine A1 and other G protein coupled receptors. The claims of the copending Application 11/576,035 are drawn to an assay using a fluorescently tagged nucleoside ligand for adenosine A1 and other G protein coupled receptors.

Therefore the present claims are obvious in view of the claims of the copending Application 11/576,035.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN BOESEN whose telephone number is 571-270-1321. The examiner can normally be reached on Monday-Friday 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTIAN BOESEN/
Examiner, Art Unit 4131

/James . Wilson/
Supervisory Patent Examiner, AU 1624